

ARGUMENTS/REMARKS

Claim 1-47 and 51-66 are currently pending in this application. Claims 3, 21-47, 51-57 and 60-64 have been canceled as directed to non-elected subject matter, without admission and without prejudice to Applicants' right to pursue the subject matter of those canceled claims in either this or other (*e.g.*, related continuing or divisional) patent applications. Claim 1 has also been canceled without prejudice or admission. Claims 2, 4-9, 11-19, 58-59 and 65 have been amended so that they now depend from independent claim 66 rather than from canceled claim 1. Hence, no new matter has been introduced in these amendments.

Upon entry of these amendments. Claims 2-20, 56-59 and 65-66 will be pending. Entry and consideration of these amendments is respectfully requested.

Election/Restriction

Claims 3, 21-47, 51-57 and 60-64 are directed to subject matter that was not elected in Applicants' response to the Restriction Requirement for this application. The Office Action indicates that a complete response to the Office Action "must include a cancellation of non-elected claims or other appropriate action." See, in the Office Action, at page 2, lines 9-10. Accordingly, claims 3, 21-47, 51-57 and 60-64 have been canceled in this amendment. However, the cancellation of these claims is made without admission and without prejudice to Applicants' rights to traverse the Requirement for Restriction and/or pursue the subject matter of the non-elected claims in either this or other (*e.g.*, related continuation or divisional) patent applications.

The Rejections Under the First Paragraph of 35 U.S.C. § 112 Should Be Withdrawn

Claim 1-2, 4-20, 58-59 and 65 have been newly rejected as failing to comply with the Written Description Requirement set forth in 35 U.S.C. § 112, first paragraph. In particular, the Examiner argues that "there is no support [in the specification] for the newly added negative proviso" introduced by Applicants' previous amendment to claim 1. In response, Applicants

substance selected from the group consisting of antigens, allergens, allergoids, peptides, proteins, haptens, carbohydrate, PNA and RNA.” The claim does not recite vaccine formulations containing *any* DNA molecule - either as an antigen itself, or encoding a particular antigen (as described by *Gonczol*).

For the foregoing reason, Applicants submit that the Examiner’s rejection of claims 1,2, 4-8, 11-13, 16, 58-59 and 66 under 35 U.S.C. 102 has been obviated, and respectfully request that the rejection be withdrawn.

The Rejections For Obviousness

Should Be (Withdrawn)

The Examiner has also rejected the pending claims under 35 U.S.C. 103(a), as being obvious over various combinations of cited references. Each of these rejections is discussed, in turn, below.

(i) Claims 9, 10, and 20

The Examiner has sustained the rejection of these claims as unpatentable over *Gonczol* in view of *Vogel et al.* (“A Compendium of Vaccine Adjuvants and Excipients” in Vaccine Design: The Subunit and Adjuvant Approach (Chapter 7), M.F. Powell & M.J. Newmann, Eds. (Plenum Press, New York) 1995, pages 141-228). As explained above, however, *Gonczol* merely teaches vaccines containing a DNA that encodes a particular antigen. Neither *Gonczol* nor *Vogel* teaches or suggests vaccines containing any of the antigens recited in pending claim 66 of this application. Applicants therefore respectfully submit that this rejection should be withdrawn.

(ii) Claims 1-2, 4-8, 11-13, 58-59, and 66

The Examiner has maintained the rejection of claims 1, 2, 4-8, 11-13, and 58-59 and rejected newly presented claim 66 as being unpatentable over *Aviram et al.* (U.S. 6,362,236) and *Conte et al.* (U.S. 5,464,633). According to the Examiner, *Conte* specifically provides the teaching that titanium

dioxide is an adjuvant. In contrast, the Applicants have asserted that *Conte* teaches that titanium dioxide is an opacity agent, a contention that the Examiner has rejected.

The Applicants respectfully traverse this rejection and request reconsideration. Based on a reexamination of the *Conte* patent, the Applicants suggest that the critical issue, which has been overlooked, is the meaning of the word “adjuvant” *as it is used in Conte*. As the analysis below will show, the term has a very general meaning in *Conte*, akin to “additive” or “ingredient” – that is in marked contrast to the specialized immunological definition of “adjuvant” in the instant application.

The instant application provides a basic definition of adjuvant that is well recognized by one skilled in the art of immunology and vaccination: “substances that, when administered together with an antigen, have the capacity to augment the immune response to the antigen.” p. 1, ll. 16-18.

Conte does not provide a formal definition of “adjuvant,” requiring extraction of the meaning from its use in the patent. As a guiding principle, §2141.02 of the MPEP states that a prior art reference must be considered in its entirety, including portions that would lead away from the claimed invention (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed Cir. 1983)).¹ Reflecting this broad consideration are the following exemplary passages, including that cited by the Examiner:

(1) Col. 4, ll. 41-45 (emphasis added):

In addition *adjuvant* substances *as* natural and/or synthetic polymeric materials belonging to the class of so called *gellable polymers, able to slow the release* of the active substance from the core, may be used.

(2) Col. 5, ll. 58-67 (emphasis added):

In the case said external layer is applied by compression diluents *as* those traditionally used in the solid forms preparation or fatty, waxy, natural and synthetic or semisynthetic substances *as* glyceryl monostearate and semisynthetic triglyceride derivatives, semisynthetic glycerides, hydrogenated castor oil, glycerylpalmitostearate, glyceryl behenate *and other adjuvants* such as *binders as* polyvinylpyrrolidone, gelatin, ethylcellulose, methylcellulose, sodium carboxymethylcellulose and other natural or synthetic substances well known to the skilled in the field, may be used

¹ Applicants respectfully submit that this need is especially critical in the analysis of *Conte*, given that English is clearly not the first language of the drafters.

Tablet as claimed in claim 1, characterized in that said *adjuvant* substances of the core are *hydrophobic diluents* selected from the group consisting of glyceryl monostearate, hydrogenated castor oil, waxes, and glycerides.

In such case besides the basic polymeric material as before described *plasticizing substances as* butylphthalate, propylphthalate, diethylphthalate, zein, polyoxyethylenglycols with different molecular weight and opacity agents as titanium dioxide and other adjuvants well known to the skilled in the field, may be used.

A broad examination of *Conte* therefore reveals that the term “adjuvant” does not have the same meaning as is has in the instant application. Rather, it has a broad meaning most akin to a “general pharmaceutical additive.” Moreover, this definition is also consistent with the general teaching of *Aviram et al.* that titanium dioxide is a common excipient or carrier. In this sense, then, both the Examiner and Applicants are correct. Titanium dioxide is an opacity agent specifically, but when in the special pharmaceutical context of *Conte*, is also an example of an “adjuvant” or pharmaceutical additive.

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(ii) Claims 14, 15, 19, and 65

The Examiner has rejected these claims as being unpatentable over the combination of (1) *Gonczol* or *Aviram*; and (2) *Conte et al.* The Applicants traverse these rejection on the basis of the claim amendments and arguments just presented. *Gonczol* and *Conte* do not teach the elements of the claimed formulations. Accordingly, the Applicants respectfully request withdrawal of this rejection.

Miscellaneous Claim Objections

Applicants note, with appreciation, that the Examiner has found the subject matter of claim 17 to be allowable. However, the Examiner has objected to this allowable claim as being dependent upon a rejected base claim – *i.e.*, claim 1. The Office Action indicates, however, that claim 17 “would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. See, in the Office Action, at page 9, lines 15-17.

In response, Applicants note that claim 1 has been canceled without prejudice or admission in this amendment. Claim 17 has been amended so that it now depends from claim 66. As explained in detail above, Applicants maintain that the subject matter of claim 66 is fully allowable and that the Examiner’s objections to that claim have been overcome. Hence, claim 17, as amended, is also allowable. For this reason, Applicants respectfully decline to amend claim 17 as suggested in the Office Action, and respectfully submit that the Examiner’s objections to that claim should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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